

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DISTRICT 1199P HEALTH AND WELFARE
PLAN on behalf of itself and all
others similarly situated,

Plaintiff,

V.

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA LP, ASTRAZENECA AB,
and AKTIEBOLAGET HASSLE,

Defendants.

C.A. No.

CLASS ACTION COMPLAINT

JURY DEMANDED

NATURE OF THE CASE

1. This is a civil antitrust action brought by Plaintiff District 1199P Health and Welfare Plan on behalf of all Third-Party Payors who purchased, paid or reimbursed for Toprol-XL in Arizona, California, District of Columbia, Florida, Iowa, Kansas, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, South Dakota, Tennessee, Vermont, West Virginia, and Wisconsin (collectively the “Indirect Purchaser States”) (for Count I) and the United States (for Count II) seeking damages arising out of the unlawful actions of AstraZeneca Pharmaceuticals LP, AstraZeneca LP, AstraZeneca AB, and Aktiebolaget Hassle (collectively “AstraZeneca” or “Defendants”).

2. Toprol-XL is an extended-release drug approved by the U.S. Food & Drug Administration (“FDA”) for treating hypertension, angina, and congestive heart failure. AstraZeneca sells this drug in 25 mg, 50 mg, 100 mg, and 200 mg dosages.

3. As described herein, AstraZeneca engaged in a scheme in which it employed fraud and/or inequitable conduct before the United States Patent and Trademark Office (“PTO”) in order to obtain two patents (U.S. Patent No. 5,001,161 (the “’161 Patent”) and U.S. Patent No. 5,081,154 (the “’154 Patent”) – which would not have issued in the absence of AstraZeneca’s fraud and/or inequitable conduct. In addition, AstraZeneca improperly procured an objectively baseless listing of the patents in the FDA’s “Orange Book” in order to assert sham patent infringement claims against any potential competitor seeking FDA approval to manufacture and sell a competing, generic version of Toprol-XL.

4. Beginning in 2003, AstraZeneca instituted litigation against companies seeking approval from the FDA to market generic versions of Toprol-XL, even though AstraZeneca knew that the ‘161 and ‘154 Patents had been improperly obtained and that no reasonable claim of infringement based on the patents could be asserted. Moreover, AstraZeneca commenced the objectively baseless patent litigation without any legitimate purpose, but solely because the commencement of the litigation would automatically delay the FDA’s granting of final marketing approval to the generic manufacturers. Without this approval, the generic manufacturers cannot lawfully enter the market.

5. By their unlawful acts, AstraZeneca has willfully and unlawfully maintained their monopoly power over Toprol-XL and its generic equivalents (the extended-release metoprolol succinate “molecule”), and thus has benefited from hundreds of millions of dollars in ill-gotten gains. Absent AstraZeneca’s unlawful conduct, less expensive, bioequivalent generic versions of Toprol-XL would have been available on the market much earlier.

JURISDICTION AND VENUE

6. This Court has jurisdiction under 28 U.S.C. §§ 1332(a) and (b), as Plaintiff is a citizen of a different state than each Defendant and the matter in controversy exceeds \$75,000,

exclusive of interest and costs, and because this is a class action and Plaintiff and one or more class members and Defendants are citizens of different states and the matter in controversy exceeds \$5,000,000.

7. The Defendants named herein are found or transact business within this district, and the interstate trade and commerce, hereinafter described, was carried out, in substantial part, in this district. Venue, therefore, is appropriate within this district under 15 U.S.C. §§ 22 and 28 U.S.C. §§ 1391(b) and (c).

THE PARTIES

8. Plaintiff District 1199P Health and Welfare Plan is an employee benefit trust fund. Plaintiff maintains its principal place of business at Suite 400, 6345 Flank Drive, Harrisburg, Pennsylvania 17112. Plaintiff at all times relevant to this action was self insured with respect to medical and prescription benefits. Plaintiff provides a prescription drug plan for approximately 2,600 participants, which covers prescriptions for Toprol-XL. Plaintiff is, therefore, a Third Party Payor for prescription drugs, including Toprol-XL.

9. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of Delaware, which distributes, markets, sells, and/or profits from pharmaceutical products, including Toprol-XL, sold throughout the United States. Its U.S. corporate headquarters is located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is a U.S. subsidiary of Astra-Zeneca PLC, and was created as a result of the union of Zeneca Pharmaceuticals and Astra Pharmaceuticals LP in the U.S. after the 1999 merger.

10. Defendant AstraZeneca LP is a limited partnership organized and existing under the laws of Delaware, with its principal place of business Wilmington, Delaware. AstraZeneca LP holds an approved New Drug Application from the United States Food and Drug

Administration (“FDA”) for extended-release metoprolol succinate preparations, which it sells under the brand name Toprol-XL. AstraZeneca LP is a U.S. subsidiary of AstraZeneca PLC.

11. Defendant Astra Zeneca AB is a corporation organized and existing under the laws of Sweden, having its principal place of business at S 151 85 Sodertalje, Sweden.

12. Defendant Aktiebolaget Hassle is a corporation organized and existing under the laws of Sweden, having its principal place of business at Molndal, Sweden. Aktiebolaget Hassle is a wholly-owned subsidiary of AstraZeneca AB.

13. Defendants’ actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants’ officers, agents, employees, or representatives while actively engaged in the management of Defendants’ affairs.

FACTUAL BACKGROUND

14. A drug manufacturer must obtain approval from the U.S. Food and Drug Administration (“FDA”) before the manufacturer may lawfully introduce a new drug (i.e., branded drug) in the United States. In order to have one its new drugs considered for approval, a manufacturer must file a New Drug Application (“NDA”) with the FDA demonstrating the safety and efficacy of the drug for its intended use. *See* 21 U.S.C. § 355(b).

15. Generic drugs are similar to branded drugs. A generic drug is comparable to a branded drug in dosage, form, strength, route of administration, quality, performance characteristics and intended use.

16. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the “Hatch-Waxman Act”), amending the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-392. Under the Food, Drug, and Cosmetics Act, new or “pioneer” drug manufacturers must obtain FDA approval for any new drug by filing a New Drug Application (“NDA”), which requires the submission of specific data

concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

17. An “AB-rated” drug is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug, and if there is no significant difference in the formulation, quality and effectiveness of the two drugs. *See* 21 U.S.C. § 355(j)(8)(B).

18. A company seeking to market an “AB-rated” generic drug may file an Abbreviated New Drug Application (“ANDA”) with the FDA. *See* 21 U.S.C. § 355(j).

19. When it is introduced in the market, the generic version of a brand-name drug is typically priced significantly below the corresponding brand-name version of that drug. As a result, purchasers and consumers substitute generic versions of the drug for some or all of their purchases. Subsequent to the introduction of the drug, prices for generic versions of a drug tend to decrease even further. This price competition enables purchasers and consumers of the drugs to: (a) purchase lower-priced generic versions of a drug in substitution for the brand; and/or (b) purchase the brand-name drug at reduced prices. Consequently, in order to maintain their sales of a brand-name drug at higher prices, brand-name drug manufacturers have a substantial financial interest in delaying and precluding generic competition.

20. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the ability to seek to exclude or prevent others from making and/or selling the new drug in the United States for the duration of the patents.

21. Under 21 U.S.C. § 355(b), a manufacturer of a new drug must list any patents that claim the drug for which FDA approval is sought or that claim a method of using the drug with

respect to which a claim of patent infringement could be reasonably asserted against an unlicensed manufacturer or seller of the drug. Once in the NDA is approved by the FDA, any such patents are listed in publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

22. Federal regulations impose strict limitations on the types of patents that an NDA holder can submit to the FDA for listing in the Orange Book. One important limitation is imposed by 21 C.F.R. § 314.53(b), which prohibits NDA holders from listing any patent in the Orange Book unless a claim of infringement could reasonably be asserted on the basis of such a patent.

23. The FDA does not employ an adjudicatory process to determine whether a patent submitted by an NDA holder qualifies for listing in the Orange Book, nor does it otherwise police the listing of patents in the Orange Book. In this regard, the FDA relies entirely upon the good faith of the NDA holder submitting the patent for listing.

24. To obtain FDA approval of an ANDA, and thus the right to sell a generic version of a branded drug, a generic manufacturer must certify that the generic drug for which it seeks approval does not infringe any patent listed in the Orange Book as claiming the branded drug. More specifically, under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

- I. The branded manufacturer has not filed patent information with the FDA;
- II. The patent or patents listed in the Orange Book have expired;
- III. The patent will expire on a date in the future, and the generic manufacturer does not seek to market its generic version of the drug prior to the date of expiration; or
- IV. The patent is invalid and not infringed by the generic manufacturer's product (a "Paragraph IV Certification").

25. In connection with filing a Paragraph IV Certification, the generic manufacturer must give notice to the NDA holder and the owner of the patent(s) at issue that it is asserting that the patent is invalid or will not be infringed.

26. The Paragraph IV certification constitutes a “technical act of infringement” under the Hatch-Waxman Act, which grants jurisdiction to the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five days from the date of the notice to institute an action against the generic manufacturer pursuant to 35 U.S.C. § 271(e)(2). The initiation of such a suit by the branded manufacturer stays the FDA’s approval of the ANDA for up to thirty months under 21 U.S.C. § 355(j)(5)(B)(iii).

27. Because of the automatic stay provisions, the filing of an infringement action in response to a Paragraph IV Certification gives the brand-name manufacturer the functional equivalent of a preliminary injunction against the generic manufacturer, blocking the entry of a generic equivalent from entering the market and protecting the branded manufacturer’s monopoly.

DEFENDANTS’ ANTICOMPETITIVE CONDUCT

28. Defendants have falsely asserted that two patents cover Toprol-XL and bar generic competition: the ‘161 Patent and the ‘154 Patent.

29. The ‘161 Patent issued on March 19, 1991, with a single claim: “A pharmaceutical composition comprising metoprolol succinate together with a sustained release pharmaceutically acceptable carrier.”

30. The ‘154 Patent issued on January 14, 1992, with a single claim: “Metoprolol succinate.”

31. The named inventors on both the ‘161 and ‘154 Patents are Curt H. Appelgren and Eva C. Eskilson. However, Appelgren and Eskilson were not the inventors of metoprolol

succinate, which had been first made at AstraZeneca before either of them joined the company and more than ten years before patent applications claiming the compound were filed in the PTO naming them as inventors.

32. As explained in detail below, when Appelgren and Eskilson tried to claim formulations of metoprolol succinate for their new employer after leaving the employ of AstraZeneca, AstraZeneca contested their right to do so and asserted its ownership to rights to metoprolol succinate in a complaint filed in the Swedish Patent Office that alleged that metoprolol succinate had been invented by its employee Toivo Nitenberg and disclosed in confidence to Appelgren and Eskilson. Several months later, Appelgren and Eskilson agreed to drop metoprolol succinate from their application, assign rights to AstraZeneca, and file a new application directed to metoprolol succinate and assign the new application to AstraZeneca.

33. In the early 1990s, Appelgren and Eskilson were employed at AstraZeneca's AB Hassle division in Molndal, Sweden. Among their duties, Appelgren and Eskilson participated in a project to develop new controlled-release formulations of metoprolol. Their duties, however, had nothing to do with the identification, synthesis, or invention of different salts of metoprolol.

34. Under the organization and procedures within the AstraZeneca organization at the time, responsibility for synthesis of alternative compounds rested with a group employed by Astra Pharmaceutical Production AB, located in Sodertalje, Sweden. Neither Appelgren nor Eskilson conceived of or synthesized metoprolol succinate. Rather, that compound was supplied to the group of which Appelgren and Eskilson were members by chemists employed by AstraZeneca in Sodertalje, including Lars Lilljequist.

35. In his deposition taken in AstraZeneca's patent litigation against potential generic competitors, Appelgren admitted that metoprolol succinate was not a newly developed product at AstraZeneca, but was an "old," known compound supplied to the product development group.

36. The other inventor, Ms. Eskilson, could not recall at her deposition why she was named an inventor of metoprolol succinate.

37. At the end of 1982, Appelgren resigned from Hassle to form his own company, Lejus Medical AB ("Lejus"). Appelgren was a founder and 25% owner of Lejus.

38. Several months later, Eskilson joined Appelgren at Lejus, and Appelgren and Eskilson began to work on developing a sustained release formulation of quinidine sulphate for a U.S. company unrelated to AstraZeneca.

39. On January 10, 1984, Lejus filed a Swedish patent application (SE8400085, the "Swedish Application") naming Appelgren and Eskilson as the inventors based on the sustained release formulation they had developed for quinidine sulphate at Lejus. When listing potentially useful pharmaceutical agents for their sustained release formulation, Appelgren and Eskilson included metoprolol succinate. Although Appelgren and Eskilson knew of metoprolol succinate from their work at Hassle, they did not believe they were violating any duty confidentiality by disclosing it in the Swedish Application because they did not believe it was a new compound and certainly did not believe they were its inventors.

40. The Lejus application was published in July of 1985 and came to the attention of Hassle and its parent, Astra AB, which on October 21, 1985, filed a complaint with the Swedish Patent Office asserting that Appelgren and Eskilson were not the inventors of metoprolol succinate and that the compound was invented by Toivo Nitenberg, a Hassle employee. At this point, Lejus had already filed a corresponding U.S. patent application (U.S. Serial No. 690,197

(the “ ‘197 Application”)), which ultimately issued as U.S. Patent No. 4,780,318 (the “ ‘318 Patent”).

41. To settle Hassle’s complaint, Lejus, Appelgren, and Eskilson agreed to assign Hassle any rights to metoprolol succinate in an agreement dated April 21, 1986 (the “Lejus/Hassle Agreement”). The Lejus/Hassle agreement was negotiated on behalf of Hassle and AstraZeneca at least by employees of AstraZeneca’s patent department, including Bengt Wurm.

42. In March of 1988, Lejus filed the U.S. patent application (U.S. Serial No. 172,897 (the “ ‘897 Application”)) that eventually issued as the ‘161 Patent, tracking almost exactly the agreed-upon language from the Lejus/Hassle agreement. Thereafter, Lejus assigned this application to Hassle.

43. By the time this application was filed in March of 1988, more than one year had passed since publication of Lejus’s Swedish Application naming metoprolol succinate and claiming sustained-release pharmaceutical formulations containing metoprolol succinate. Thus, Hassle knew that unless the applications issuing as the ‘161 and ‘154 Patents could rely on the filing date of the Swedish Application, any new claims in the ‘161 and ‘154 Patents to metoprolol succinate or sustained-release formulations of it would be unpatentable, *inter alia*, as anticipated by the Swedish Application, pursuant to 35 U.S.C. §§ 102(b), 119(a). They would have been unpatentable as anticipated because of other prior art as well, including an article published in 1987 and two other patent applications filed by Hassle.

44. Thus, Hassle knew that if it identified Nitenberg as the inventor of the ‘161 and ‘154 Patents, because Nitenberg is not an inventor on the ‘897 application and the Swedish Application, then Hassle would not be able to rely on the filing date of the Swedish Application for the ‘161 and ‘154 Patents and those patents would be rejected by the PTO or invalidated in litigation.

45. Hassle knew that in order to obtain U.S. patents directed to metoprolol succinate and avoid the bar of the published Swedish Application, it had to file fraudulently in the names of Appelgren and Eskilson in order to make a (fraudulent) claim of priority. Hassle did just this.

46. Appelgren, Eskilson, the representatives prosecuting the applications, employees of Hassle and AstraZeneca, and others involved in the prosecution of the '161 and '154 Patents knew that Appelgren and Eskilson were not the joint inventors of metoprolol succinate or the subject matter claimed in the Patents.

47. During the prosecution of the '161 and '154 Patents, Defendants did not disclose to the PTO its complaint to the Swedish Patent Office dated October 21, 1985, the Lejus/Hassle Agreement, the facts leading to these documents, or that Toivo Nitenberg had made metoprolol succinate in 1971.

48. During the prosecution of the '161 and '154 Patents, Defendants intentionally made other material misrepresentations and omissions, including in submitting a declaration of an employee, John Anders Sandberg (the "Sandberg Declaration"). Among other things, although the Sandberg Declaration extols the virtue of metoprolol succinate for use in once-daily, controlled-release preparations, Defendants did not explain that its alleged virtues were unique to a particular formulation developed by Sandberg, unrelated to any work done by Appelgren and Eskilson. The Sandberg Declaration also omits material information known to Dr. Sandberg and Defendants about prior art and the performance of other metoprolol salts.

49. Because the facts and information that Defendants failed to disclose and/or misrepresented to the PTO directly relate to proper inventorship and derivation and would have precluded patentability under, at least, 35 U.S.C. § 102(f), they were of the highest materiality.

50. These omissions and/or misrepresentations were purposeful. They were made with an intent to deceive and did, in fact, deceive the PTO, resulting in the issuance of the '161 and '154 Patents.

51. Claim 8 of Defendants' '318 Patent, which issued on October 25, 1988 (expiring on October 25, 2005), claims, among other compounds, "metoprolol succinate."

52. The claims of the '161 and '154 Patents also claim "metoprolol succinate," but are due to expire on March 18, 2008, which is more than 17 years after the issuance of the '318 Patent.

53. Defendants knew that the Patent Act (as it existed when the '318 patent was filed) entitled them only to 17 years of patent protection for metoprolol succinate and that the Patent Act prohibited them from "double patenting" metoprolol succinate in order to obtain more than 17 years of patent protection. However, Defendants did not file any terminal disclaimers limiting the patent monopoly for metoprolol succinate to 17 years.

54. Because Defendants did not file terminal disclaimers of the '161 and '154 Patents, the Patents are invalid for obviousness-type double patenting due to Claim 8 of the '318 Patent, and Defendants knew this.

55. On November 21, 2003, Defendants filed a statutory disclaimer of Claim 8 of the '318 Patent, effectively canceling the claim. By filing the statutory disclaimer of Claim 8 of the '318 Patent, instead of filing terminal disclaimers of the '161 and '154 Patents, Defendants wrongfully and in bad faith attempted to circumvent double-patenting invalidity of the '161 and '154 Patents and obtain more than 17 years of patent protection for metoprolol succinate.

56. Defendants' filing of the statutory disclaimer of Claim 8 to overcome the obviousness-type double patenting invalidity of the '161 and '154 Patents is objectively baseless and was not done for any legitimate purpose. This filing was, thus, a sham.

57. Despite Defendants' knowledge that the '161 and '154 Patents were invalid, Defendants caused the patents to be listed in the Orange Book as covering Toprol-XL and as reasonably giving rise to a claim of infringement. Further, Defendants did not withdraw these Orange Book listings even after being provided with clear proof that they were improper. The Orange Book listings were objectively baseless.

58. Defendants knew that under the Hatch-Waxman Act, if they sued to enforce patents listed in the Orange Book, they would (a) receive the functional equivalent of an automatic injunction that would last up to thirty months, or more, (b) bar generic competitors from marketing extended-release metoprolol succinate products without any proof of likelihood of success, and regardless of the invalidity of the listed patents or the baselessness of the suit, and (c) delay FDA action, attention to, and approval of ANDAs filed by generic competitors.

59. Defendants' decisions to cause the patents to be listed, not to inform the FDA that the '161 and '154 Patents were invalid, and not to withdraw the Orange Book listings, were intentionally deceptive.

60. Despite Defendants' knowledge that the '161 and '154 Patents were invalid, starting in May, 2003 Defendants commenced litigation based on these Patents against the following companies seeking to market bioequivalent, generic versions of Toprol-XL: KV Pharmaceutical Co., Andrx Pharmaceuticals, LLC, Andrx Corp., and Eon Labs, Inc. (collectively, the "Generic Manufacturers"). The litigation (the "Patent Litigation") was ultimately transferred to the United States District Court for the Eastern District of Missouri for pretrial proceedings.

61. Knowing that the Patent Litigation was objectively baseless and a sham, Defendants nonetheless commenced and maintained the actions deceptively, in bad faith, and

with the specific intent and subjective motivation to prevent the Generic Manufacturers from selling competing extended-release metoprolol succinate products.

62. Defendants knew that even though ultimately they could not expect success on the merits of the Patent Litigation, the process itself of commencing the sham litigation would nonetheless enable them automatically to bar the generic manufacturers from coming to market for up to thirty months or more, under 21 U.S.C. § 355(j)(5)(b)(iii).

63. Defendants' lawsuits were shown to be a sham. On January 17, 2006, United States District Judge Rodney W. Sippel granted summary judgment for the Generic Manufacturers, determining, *inter alia*, any reasonable jury was bound to find that clear and convincing evidence established that (1) the '161 and '154 Patents were invalid for double-patenting based on Claim 8 of the '318 Patent, and (2) the '161 and '154 Patents were unenforceable because of AstraZeneca's misconduct in not informing the patent examiner about the dispute regarding inventorship while prosecuting the patents. On the latter point, Judge Sippel found that the inventorship issue was "highly material" to patentability and that AstraZeneca's intent to deceive was "clearly present."

64. Defendants' conduct during the Patent Litigation further evinces their anticompetitive intent. For example, Judge Sippel noted that, during the litigation, Defendants "maintained a pattern of submitting witness declarations that contradict their own prior deposition testimony."

DEFENDANTS'S CONDUCT FORECLOSED GENERIC COMPETITION

65. Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Defendants to sell Toprol-XL without generic competition. But for Defendants' illegal conduct, one or more generic competitors would have begun marketing AB-

rated generic versions of Toprol-XL much sooner than they actually will be marketed, and, at all events, would have been on the market no later than May 5, 2005.

66. The generic manufacturers seeking to sell generic Toprol-XL have extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs and marketing generic pharmaceutical products. Eon Labs, Inc. ("Eon"), for example, has a history of achieving high approval rates for its ANDAs, usually within twelve to thirteen months of filing an ANDA.

67. Eon has publicly affirmed its intention and ability to begin selling generic Toprol-XL upon approval of its ANDA. However, Defendants' unlawful conduct has caused the ANDA approval process to be delayed by the FDA, and caused the generic manufacturers to divert resources from their ANDA applications and to expend unnecessary resources on litigation. Another potential generic manufacturer, Andrx, has recently had its pending drug applications placed on hold, which would not have affected its extended-release metoprolol succinate ANDA absent Defendants' causing delay.

68. Absent the Patent Litigation, which imposed the stay of final ANDA approval, the Generic Manufacturers and the FDA would have had reason to, and would have, focused upon and poured resources into the ANDA approval process for generic extended-release metoprolol succinate. Such focus and resources would have brought far earlier FDA approval and far earlier marketing of generic Toprol-XL.

69. Defendants' illegal acts to delay the introduction into the U.S. marketplace of any generic version of Toprol-XL caused Plaintiff and the Class to pay more than they would have paid for extended-release metoprolol succinate, absent Defendants' illegal conduct.

70. If generic competitors had not been unlawfully prevented from earlier entering the market and competing with Defendants, direct purchasers, such as Plaintiff, would have paid less

for extended-release metoprolol succinate by (a) substituting purchases of less-expensive AB-rated generic extended-release metoprolol succinate for their purchases of more-expensive branded Toprol-XL, (b) receiving discounts on their remaining branded Toprol-XL purchases, and (c) purchasing generic extended-release metoprolol succinate at lower prices sooner.

71. Moreover, because of Defendants' objectively baseless Orange Book listings, once the generic manufacturer that filed first for a particular dosage strength begins to sell its generic version of Toprol-XL, it will be entitled to 180 days of generic marketing exclusivity for that dosage strength. This process delays the entry of other generic competitors into the market and further forestalls price competition, competition that would have existed but for Defendants' wrongful conduct.

72. Due to Defendants' conduct, other generic manufacturers were discouraged from and/or delayed in developing generic versions of Toprol-XL.

73. Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

MONOPOLY POWER

74. Defendants have monopoly power over Toprol-XL and its generic equivalents, because they have had the power to maintain the price of Toprol-XL at supracompetitive levels profitably, without losing substantial sales.

75. A significant, non-transitory price increase by Defendants of Toprol-XL would not have caused a significant loss of sales to other products.

76. Defendants need to control only Toprol-XL and its AB-rated generic equivalents in order to maintain the price of Toprol-XL profitably and supracompetitive levels.

77. In addition, Defendants have sold Toprol-XL at prices well in excess of marginal costs and enjoyed high profit margins.

78. Moreover, Defendants have had, and exercised, the power to exclude competition.

79. To the extent that defining a relevant product market is necessary in this case, the relevant product market is Toprol-XL and its AB-rated generic equivalents. The relevant geographic market is the United States.

80. Defendants currently hold a 100% share in the relevant product market in the United States.

81. Plaintiff and others similarly situated continue to pay higher prices for their extended-release metoprolol succinate reimbursements and purchases than they would otherwise have paid, as a result of AstraZeneca's unlawful and willful acquisition and/or maintenance of its monopoly power as alleged herein.

ANTITRUST IMPACT UPON PLAINTIFF AND MEMBERS OF THE CLASS

82. During the relevant period, Plaintiff and members of the Class paid or reimbursed for substantial amounts of Toprol-XL from Defendants. As a result of Defendants' illegal conduct, members of the Class paid or reimbursed artificially inflated prices for extended-release metoprolol succinate. Those prices were substantially greater than the prices that members of the Class would have paid or reimbursed absent the illegal conduct alleged herein, because: (1) the price of brand-name Toprol-XL was artificially inflated by Defendants' illegal conduct and/or (2) Defendants precluded lower-priced generic versions of extended-release metoprolol succinate from reaching the market sooner.

TRADE AND COMMERCE

83. At all material times, Toprol-XL was sold throughout the United States and shipped across state lines and sold by AstraZeneca to customers located outside the state of manufacture. The activities of Defendants as charged in this complaint were within the flow of, and have substantially affected, interstate commerce.

ANTICOMPETITIVE EFFECTS

84. As a direct and proximate result of the illegal conduct alleged herein, AstraZeneca deprived Plaintiff and the Class it seeks to represent of competition that the federal and state laws are designed to promote, preserve, and protect.

CLASS ACTION ALLEGATIONS

85. Plaintiff brings this action on behalf of itself and, under Rule 23(b)(2) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of a class defined as follows:

All Third Party Payors in the United States who purchased, reimbursed and/or paid for Toprol-XL from May 5, 2005 until the date the effects of Defendants' anticompetitive conduct has ended (the "Class Period"). "Third-Party Payor" shall mean any non-governmental entity that is: (i) a party to a contract, issuer of a policy, or sponsor of a plan, which contract, policy or plan provides prescription drug coverage to natural persons; and (ii) is also at risk pursuant to such contract, policy or plan, to provide prescription drug benefits, or to pay or reimburse all or part of the cost of prescription drugs dispensed to natural persons covered by such contract, policy or plan. Excluded from the class are Defendants, their parents, subsidiaries and affiliates, and all governmental entities (the "Class").

86. Members of the Class are so numerous that joinder of all members is impracticable.

87. Plaintiff's claims are typical of the Class. Plaintiff and all members of the Class were injured and continue to be injured and/or threatened with injury in the same manner by Defendants' unlawful, anticompetitive acts, i.e., they have paid and reimbursed for and continue to pay and reimburse for supracompetitive prices for Toprol-XL and will continue to be forced to do so until Defendants' illegal conduct ceases.

88. Plaintiff will fairly and adequately represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

89. Plaintiff is represented by counsel who are experienced and competent in the prosecution of antitrust class actions.

90. Defendants have acted on grounds generally applicable to the class, thereby making appropriate final injunctive relief with respect to the class a whole.

91. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class.

92. Questions of law and fact common to the Class include:

- a. Whether Defendants unlawfully excluded competitors and potential competitors from the market for Toprol-XL and generic bioequivalent to Toprol-XL;
- b. Whether Defendants maintained or attempted to maintain monopoly power by delaying entry in the relevant market;
- c. Whether Defendants' litigation asserting infringement of the '161 and '154 Patents was objectively baseless;
- d. Whether Defendants made fraudulent representations to the PTO regarding the '161 and '154 Patents;
- e. The amount of the overcharges to members of the Class for Toprol-XL over and above the amounts they would have paid or reimbursed for that drug in a competitive market unaffected by Defendants' illegal conduct as alleged herein; and
- f. Whether Defendants were unjustly and enriched by reason of the unlawful conduct alleged herein and if so the amount that they were unjustly enriched.

93. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class

mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

94. Plaintiff knows of no difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIOLATIONS CLAIMED

COUNT I

FOR COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES

95. Plaintiff incorporates by reference the allegations set forth above, as if fully set forth herein.

96. Defendants knowingly and intentionally engaged in an anticompetitive scheme designed to obtain by fraud the '161 and '154 Patents and willfully maintain monopoly power. The scheme included obtaining the '161 and '154 Patents by committing fraud and/or inequitable conduct before the PTO, improperly listing the '161 and '154 Patents in the Orange Book, and improperly filing and prosecuting the objectively baseless litigation against generic manufacturers. Defendants' unlawful scheme was designed to delay the entry of generic versions of Toprol-XL to the market.

97. By this scheme, Defendants intentionally and wrongfully maintained their monopoly power with respect to Toprol-XL in violation of federal and state law. As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid and/or reimbursed artificially inflated prices for extended-release metoprolol succinate.

98. Plaintiff and members of the Class have been injured in their business or property by Defendants' antitrust violations. Their injury consists of having paid or reimbursed for, and

continuing to pay or reimburse for, higher prices for extended release metoprolol succinate than they would have paid or reimbursed in the absence of those violations.

99. Defendants' unlawful conduct alleged herein violates the following states' laws:
 - i. Arizona: The aforementioned practices by Defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §§44-1401, *et seq.*, and the Constitution of the State of Arizona, Article 14, §15;
 - ii. California: The aforementioned practices by Defendants were and are in violation of the Cartwright Act, California Business and Professions Code §§ 16700, *et seq.* and the California Unfair Competition Act, California Business and Professions Code §§17200, *et. seq.*;
 - iii. District of Columbia: The aforementioned practices by Defendants were and are in violation of the District of Columbia Restraint of Trade Act, D.C. Code §§28-4501, *et seq.*,
 - iv. Florida: The aforementioned practices by Defendants were and are in violation of the Florida Antitrust Act, Chapter 542 and the Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II, *et seq.*;
 - v. Iowa: The aforementioned practices by Defendants were and are in violation of the Iowa Competition Law, Iowa Code, §§ 553.1, *et seq.*;
 - vi. Kansas: The aforementioned practices by Defendants were and are in violation of the Kansas Unfair Trade and Consumer Protection Act, KSA §§ 50-101, *et seq.*;
 - vii. Louisiana: The aforementioned practices by Defendants were and are in violation of the Louisiana Revised Statutes §§ 51:137, *et seq.*;
 - viii. Maine: The aforementioned practices by Defendants were and are in violation of the Maine Trade Regulation Law of 1954, 10 M.R.S.A. §§ 1101, *et seq.*, and the Maine Unfair Trade Practices Act, 5 M.R.S.A. §205-A, *et. seq.*;
 - ix. Massachusetts: The aforementioned practices by Defendants were and are in violation of the Massachusetts Consumer Protection Act, M.G.L Ch. 93A, *et seq.*;
 - x. Michigan: The aforementioned practices by Defendants were and are in violation of the Michigan Antitrust Reform Act, MCL §§ 445.771, *et seq.*;
 - xi. Minnesota: The aforementioned practices by Defendants were and are in violation of the Minnesota Antitrust Act of 1971, Minn. Stat. §§ 325D.49, *et seq.*;
 - xii. Mississippi: The aforementioned practices by Defendants were and are in violation of the Miss. Code Ann. §§ 75-21-1, *et seq.*;

- xiii. Nebraska: The aforementioned practices by Defendants were and are in violation of the Nebraska antitrust statute, Neb. Rev. Stat. §§ 59-801, *et seq.*;
- xiv. Nevada: The aforementioned practices by Defendants were and are in violation of the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. §§ 53:598A, *et seq.*;
- xv. New Mexico: The aforementioned practices by Defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §§ 57-1-1, *et seq.*;
- xvi. New York: The aforementioned practices by Defendants were and are in violation of the New York Donnelly Act, GBL §§ 340, *et seq.* and/or New York General Business Law §349;
- xvii. North Carolina: The aforementioned practices by Defendants were and are in violation of the North Carolina's antitrust law, N.C.G.S. §§ 75-1, *et seq.*;
- xviii. North Dakota: The aforementioned practices by Defendants were and are in violation of the North Dakota's antitrust law, North Dakota Cent. Code §§ 51-08.1, *et seq.*;
- xix. South Dakota: The aforementioned practices by Defendants were and are in violation of the South Dakota antitrust law, SDCL ch. 37-1, *et seq.*;
- xx. Tennessee: The aforementioned practices by Defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §§ 47-25-101, *et seq.*, and the Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101, *et seq.*;
- xxi. Vermont: The aforementioned practices by Defendants were and are in violation of the Vermont antitrust law, Vermont Stat. §§ 2453, *et seq.*;
- xxii. West Virginia: The aforementioned practices by Defendants were and are in violation of the West Virginia Act, Chapter 47, Article 18, Section 1, *et seq.*, West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-1-101, *et seq.*; and
- xxiii. Wisconsin: The aforementioned practices by Defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stats §§ 133.01, *et seq.*

100. Defendants' conduct alleged herein violates the laws referenced in the previous paragraph.

101. Plaintiff and the Class seek damages as permitted by law caused by Defendants' violations of the state laws referenced above.

102. Plaintiff and the Class seek multiple damages as permitted by law caused by Defendants' intentional and/or flagrant violations of the state laws referenced above.

COUNT II

**FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST FOR
UNJUST ENRICHMENT BY DEFENDANTS**

103. Plaintiff incorporates by reference the allegations set forth above, as if fully set forth herein.

104. Defendants have benefited from the unlawful, anti-competitive and inequitable conduct as alleged herein.

105. Plaintiff and the Class, to their economic detriment, have conferred upon Defendants an economic benefit in the nature of profits resulting from supra-competitive prices paid or reimbursed by Plaintiff and the Class.

106. The supra-competitive prices paid or reimbursed by the Plaintiff and the Class for Toprol-XL are the result of Defendants' anti-competitive conduct, as alleged above.

107. The inequitably-obtained monies held by Defendants rightfully belong to Plaintiff and the Class, because Plaintiff and the Class paid or reimbursed illegally inflated prices for Toprol-XL indirectly to Defendants during the Class Period.

108. It is inequitable for Defendants to be permitted to retain any of the Plaintiff's and the Class's overpayments derived from Defendants' unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class pray for judgment against all Defendants, jointly and severally, as follows:

- a. certifying the Class pursuant to Rules 23(a), 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure, certifying Plaintiff as representative of the Class and designating its counsel as counsel for the Class;

b. awarding Plaintiff and the Class multiple damages, jointly and severally, for Defendants' violations of the laws in the Indirect Purchaser States, where permitted, in an amount to be determined at trial;

c. granting Plaintiff and the Class equitable relief in the nature of disgorgement, restitution and the creation of a constructive trust to remedy Defendants' unjust enrichment;

d. granting Plaintiff and the Class the costs of prosecuting this action, together with interest and reasonable attorneys' fees and costs; and

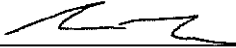
e. granting such other relief as this Court may deem just and proper under the circumstances.

DEMAND FOR JURY

Plaintiff demands trial by jury on all issues so triable.

Dated: March 31, 2006

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Attorneys for Plaintiff

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS **DISTRICT 1199P HEALTH AND WELFARE PLAN,** on behalf of itself and all others similarly situated,

(b) County of Residence of First Listed Plaintiff **Dauphin Co., PA**
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number) **302-656-2500**
Chimicles & Tikellis LLP, One Rodney Sq.,
Wilmington, Delaware 19801

DEFENDANTS **ASTRAZENECA PHARMACEUTICALS LP,**
ASTRAZENECA LP, ASTRAZENECA AB,
AKTIEBOLAGET HASSLE

County of Residence of First Listed Defendant _____

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☒ Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(n)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input type="checkbox"/> 400 State Reapportionment <input checked="" type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify)
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

Cite the U.S. Civil Statute under which you are filing. (Do not cite jurisdictional statutes unless diversity):
28 U.S.C. §§ 1332 (a) and (b)

VI. CAUSE OF ACTION

Brief description of cause: **Civil antitrust action in connection with the monopolization of Toprol-XL**

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND \$

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE **GMS**

06-52; 06-63; 06-71; 06-79;
DOCKET NUMBER **06-102**

DATE

SIGNATURE OF ATTORNEY OF RECORD

3-31-06



Robert R. Davis (#4536)

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____